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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/189,043	11/09/1998	SCOTT M. ROCKLAGE	238/117	5059

21834 7590 11/24/2004

BECK AND TYSVER  
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EXAMINER

HARTLEY, MICHAEL G

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No. 09/189,043	Applicant(s) ROCKLAGE ET AL.	
	Examiner Michael G. Hartley	Art Unit 1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 12 October 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 31-38 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-38 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/12/2004 has been entered.

***Response to Amendment***

The amendment filed 10/12/2004 has been entered. Claims 31-38 are pending herein.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 31-38 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The subject matter of claims 31-36 was not described in the specification. For example, the specification fails to describe the method of "collecting temporally spaced sets of 3-D and 2-D data, each data set collected serially throughout an acquisition or collection time; comparing 3-D and 2-D data from temporally spaced set of data by evaluating 2-D or 3-D temporally acquired images to assess the blood flow or angiographic abnormality or variation" as now recited in the claims. The specification also fails to describe any of the limitations set forth in claims 32-36 because there is no description of a physician to visually examine 3-D and 2-D data or software to quantitatively manipulate such data. Also, the time frames set forth in claims 34-35 have are not described. Also, in claim 36, such sequences are not described for the method as set forth in claim 31. While the disclosure describes spin echo and various imaging modalities, there is

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nothing to show that applicant envisioned a method wherein the collection, comparison and evaluation of 2-D and 3-D data is employed, as recited in the instant methods.

In claims 37 and 38, the recitation of "single shot imaging procedure" was not described in the specification. There is nothing in the specification which describes such an imaging modality, in fact, the specification describes taking a series of temporally spaced images, but not with a single shot.

Additionally, the new limitations set forth in claim 31 in the amendment filed 10/12/2004 do not have support in the specification. There is no description of forming a time sequence of image data including early image data and later image data or comparing ones of said early image data with ones of said later image data as now claimed.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 31-38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 31, the recitation of, forming a time sequence of image data including early image data and later image data as well as comparing such early and later data is confusing. It is unclear what is meant by "early image data" as early is a relative term. It is unclear what the reference point of early constitutes. For example, with no given time for a party to start, it would be unclear what would constitute being early for the party. The term early is not defined in the specification to give a clear meaning of this term. Therefore, it is unclear what is meant by the recitations concerning early and later images.

The dependent claims fall therewith.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982);

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*In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 15 of U.S. Patent No. 5,190,744. Although the conflicting claims are not identical, they are not patentably distinct from each other because the pending claims are encompassed by the patented claims, that is, the pending claims are drawn to a method which is anticipated by the patented claims. For example, the pending claims only differ as they recite specific imaging modalities that are employed, including fast imaging. Such fast imaging modalities are encompassed by the patented claims as shown by claim 15. Also, the instant claims are drawn to methods wherein the subjects are "humans" while the patented claims include both human and non-human subjects.

### ***Specification***

The specification fails to include a section under "Brief Description of the Drawings" as required to describe the figures filed with the application.

### ***Response to Arguments***

Applicant's arguments filed 10/12/2004 have been fully considered but they are not persuasive.

Applicant asserts that the claimed limitations are inherent and states that they will be happy to provide a declaration to further describe the inherence of the limitations within the ranges specified in the experiments.

This is not found persuasive because the cited column does not show support for comparing both 3-D and 2-D data, but only determining the signal ratio for each pixel and voxel.

Determining the signal ratio would not provide a showing that applicant envisioned the comparison and

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evaluation of data as now claimed, let alone the acquiring of temporally spaced 3D and 2D data for comparison and evaluation. Also, there is nothing to show the limitations of such an evaluation step wherein a physician evaluates a comparison of 2D and 3D data or the use of software for such a comparison and evaluation. Also, it is noted that the claim does not specifically state what the 3D and 2D data are compared to, thus, it was viewed that the 2D data was compared with the 3D data. However, there is no such specific comparison disclosed in the specification. Further, there is nothing in the specification of forming a time sequence of image data including early image data and later image data or comparing ones of said early image data with ones of said later image data as now claimed. These do not appear to be described by "the inherence of the limitations within the ranges specified in the experiments" as asserted as these limitations are not ranges, but are specific steps.

Also, applicant has failed to suggest wherein support is provided for the software as set forth in claim 33. The use of software cannot be said to be an inherent limitation, as this requires a specific step of using software. Also, in claim 36, such sequences are not described for the method as set forth in claim 31. The broad recitation of "an MRI technique" does not provide support for any possible MRI technique which may be known. There is nothing to show that applicant envisioned a method wherein the collection, comparison and evaluation of 2-D and 3-D data is employed, or the specific sequences in the claims. Further, in claims 37 and 38, the recitation of "single shot imaging procedure" was not described in the specification. There is nothing in the specification which describes such an imaging modality, in fact, the specification describes taking a series of temporally spaced images, but not with a single shot. Again, the broad recitation of an MRI technique does not show support for every variation thereof that may be possible, without some description that such variations were envisioned at the time of filing. The arguments fail to discuss how the various limitation are inherent, as many are specific methods and steps. The broad recitation of MRI does not describe all specific variations of MRI that may be performed. What may be obvious from the prior art does not provide adequate written description under 35 US 112, first paragraph.

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### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Omum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 37 and 38 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 15 of U.S. Patent No. 5,190,744, for the reasons set forth in the office action mailed 7/28/2003.

Applicant asserts that the examiner has made a provisional rejection.

It is noted that this is not a provisional rejection as the double patenting rejection is based on a patent and not another US application. However, applicant's statement of filing a terminal disclaimer upon the indication of otherwise allowable claims is acknowledged.

### ***Conclusion***

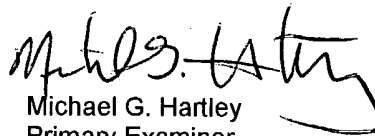
No claims are allowed at this time. However, the instant claims are free of the art of record. The prior art fails to teach or suggest method of detecting blood flow or angiographic abnormalities having the steps of imaging and acquiring, comparing and evaluating the 2-D and 3-D data as claimed in claim 31-36 or the methods of quantitatively evaluating blood flow abnormalities as set forth in claims 37-38.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael G. Hartley whose telephone number is (571) 272-0616. The examiner can normally be reached on M-Tu and Th-F, 7:30-4, Telework on Wed..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on (571) 272-0887. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

  
Michael G. Hartley  
Primary Examiner  
Art Unit 1616

11/19/2004